UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GARRY GILL, individually and on behalf of all others similarly situated, Plaintiff, v. BLUEBIRD BIO, INC., ANDREW OBENSHAIN, CHRISTOPHER KRAWTSCHUK, and RICHARD A. COLVIN, Defendants.	)	Civil Action No. 24-cv-10803-PBS

MEMORANDUM AND ORDER

May 23, 2025

Saris, D.J.

INTRODUCTION

Lead Plaintiff Larry Cattran brings this putative securities fraud class action against Defendant bluebird bio, Inc. ("bluebird") and three of its executives. In 2023, bluebird submitted a Biologics License Application ("BLA") to the Food and Drug Administration ("FDA") for Lyfgenia, or "lovo-cel," a treatment for sickle cell disease ("SCD"). Although the FDA approved the BLA, it denied bluebird's accompanying request for a priority review voucher ("PRV") and required the company to include a "black box warning" on lovo-cel's label regarding a risk of blood

cancers. bluebird's stock dropped upon its announcement of the terms of the FDA's approval.

Plaintiff alleges that, while the BLA was pending, Defendants made false or misleading statements regarding the possibility that the FDA would require a black box warning, the relationship between lovo-cel and blood cancers, and the chance that the FDA would award a PRV. He brings claims under (1) section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5; and (2) section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). Defendants now move to dismiss the amended complaint under Federal Rules of Civil Procedure 12(b)(6) and 9(b).

After hearing, the Court **ALLOWS** the motion to dismiss (Dkt. 32).

BACKGROUND

The facts are drawn from the well-pleaded allegations in Plaintiff's amended complaint. See Shash v. Biogen, Inc., 84 F.4th 1, 6 (1st Cir. 2023). Defendants have also submitted various documents in support of their motion, including transcripts of the presentations and earnings calls in which the allegedly false or misleading statements were made and certain documents referred to in the amended complaint. Plaintiff does not dispute that the Court can consider this extrinsic evidence at this stage. See id. at 6 n.2 (considering on a motion to dismiss full transcripts of the

earnings calls that allegedly contained misleading statements); Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 30 n.2 (1st Cir. 2022) (same for "documents . . . incorporated by reference" into the complaint).

I. bluebird and the Development of Lovo-Cel

bluebird is a publicly traded biotechnology company that develops gene therapies for severe genetic diseases. At all relevant times, bluebird's leadership included Defendants Andrew Obenshain, the Chief Executive Officer; Christopher Krawtschuk, the Chief Financial Officer; and Richard Colvin, the Chief Medical Officer.

bluebird experienced cash flow problems in the years predating submission of the lovo-cel BLA. The company had developed Zynteglo, a treatment for transfusion-dependent beta-thalassemia. When the German government rejected a $2 million per patient price tag for Zynteglo, bluebird closed its European operations. The FDA approved Zynteglo in August 2022, but bluebird only had the capacity to treat one patient per week. According to a confidential witness ("CW"), the company announced internally in June 2023 that it "would need a cash infusion and only had enough money to continue operations through February 1, 2024." Dkt. 26 ¶ 29.

In order to increase profits, bluebird "began using the information, processes, and technology from [its] prior drugs to create nearly identical drugs to cure different diseases." Id.

¶ 33. One such therapy was lovo-cel, which "was merely Zynteglo repackaged to treat a new disease [SCD] and bring in additional revenue." Id. ¶ 35. Zynteglo and lovo-cel share an active ingredient.

As lovo-cel was in the works, bluebird learned that a competitor, Vertex Pharmaceuticals, Inc. ("Vertex"), was developing a competing therapy for SCD. Vertex's therapy relied on newer generation technology that was safer and cheaper than the technology used for lovo-cel.

II. Submission of the Lovo-Cel BLA

On April 24, 2023, bluebird announced the submission of its BLA for lovo-cel. bluebird sought approval for certain patients ages twelve and older with SCD. The BLA included a request for priority review, which shortens the standard review timeline from ten months to six months. The FDA granted this request in June 2023. bluebird also applied for a PRV in connection with the lovo-cel BLA. Awarded to incentivize the development of certain specialized therapies, PRVs are transferable vouchers issued by the FDA that can be redeemed for guaranteed priority review of a future drug or biologic application. See 21 U.S.C. § 360ff(a)(1)-(2), (b)(1)-(2); U.S. Gov't Accountability Office, GAO-20-251, Drug Development: FDA's Priority Review Voucher Programs 5-9 (2020), https://www.gao.gov/assets/gao-20-251.pdf. A biologic for a rare pediatric disease like SCD is eligible for a PRV only if it

"contains no active ingredient that has been previously approved in any other [biologic] application." 21 U.S.C. § 360ff(a)(4)(B)(ii)(I).

bluebird's press release announcing the BLA submission mentioned adverse events that occurred during the lovo-cel clinical trials. The company disclosed that "[s]erious adverse events related to lovo-cel included anemia in two patients (4%) with alpha-thalassemia, and leukemia in two patients (4%), not resulting from insertional oncogenesis." Dkt. 34-2 at 2. Insertional oncogenesis is cancer that occurs when the vectors in a gene therapy insert in or near cancer-causing genes. The press release also noted that "[t]hree of 50 patients (6%) died, one due to sudden cardiac death and two due to leukemia." Id. bluebird changed the transplant procedure used to administer lovo-cel following the two leukemia cases.

III. Public Statements About the Lovo-Cel BLA

Obenshain and another bluebird executive were interviewed at a healthcare conference on May 11, 2023. The interview included the following exchange about the lovo-cel BLA:

> [Analyst:] . . . Any specific elements of the label that you feel like are important one way or another in terms of being market limiting or giving you more latitude to operate in the space[?]
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> [Obenshain:] . . . In terms of the label, I don't think there's any one particular area that the FDA would focus on overall. I think the -- if we look back at our ZYNTEGLO [advisory committee], it was the efficacy and

> safety, which is pretty standard. So I don't think there's any one element that they're going to actually hold [sic] in on versus others.

Dkt. 34-4 at 8.

During bluebird's second quarter 2023 earnings call on August 8, 2023, the company's executives were asked about the application for a PRV in connection with the lovo-cel BLA:

> [Analyst:] . . . [C]an you just remind me if you do get approved for sickle cell disease, will you receive the PRV? And if so, are you planning to monetize it?
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> [Krawtschuk:] . . . [I]t's possible we could receive a PRV since lovo-cel BLA was accepted for priority review for patients 12 and over. However, as it relates to whether or not we'd monetize it, we of course[] would look at the market, evaluate the opportunities in the market and then make a decision based upon what we see there. I don't want to comment today on whether or not -- we monetize it or not until we know whether or not we get a fair price for it. And just as a reminder, the PRV is not factored. Any potential PRV is not factored into our cash runway.

Dkt. 34-5 at 15-16.

bluebird held its third quarter 2023 earnings call on November 7, 2023. When discussing the company's financial position, Krawtschuk noted that bluebird had "entered into an advanced agreement to sell a [PRV], if granted, for lovo-cel for sickle cell disease for $103 million," which "would be an important source of non-dilutive capital and ha[d] the potential to strengthen [the company's] financial position ahead of the anticipated launch of

lovo-cel." Dkt. 34-6 at 7. Obenshain had the following exchanges with analysts on the same call:

> [Analyst:] . . . First, could you talk about whether for the BLA [f]or lovo-cel, whether you're in the labeling discussion stage with the FDA?
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> [Obenshain:] . . . So on the BLA, we don't comment on ongoing interactions with the agency. So we've submitted for the lovo-cel the treatment [sic] of patients with sickle cell disease i[n] 12 and older who have a history of vaso-occlusive events, and we are confident in the robustness and maturity of our BLA package and the review process.
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> [Analyst:] . . . And then maybe on safety. Any update on the 2 patients that develop[ed] [acute myeloid leukemia ("AML")] in the trial for sickle cell disease? Wondering if you could comment on how they're doing today and maybe bigger picture, whether there is a scenario where you get a label that includes risk of secondary malignancies while your competitor does not? And if that's a scenario, how should we think about implications for the launch?
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> [Obenshain:] . . . [J]ust on the safety issues. As a reminder, there have been no cases of insertional oncogenesis with lovo-cel. However, there have been cases of cancer related to the transplant procedure involving lovo-cel. And unfortunately, 2 of those patients in our early clinical trials where we -- our procedures were in the earlier phase of Generation 1 procedure since the Group A did develop leukemia and AML, and those 2 patients did pass away. So although they are not -- those 2 patients are not in our efficacy data set, it is likely that we will have a mention of that in the safety events in the label. In what part of the label or where is yet to be determined, but certainly, they will be in there. That's something that we've known for quite a while.

> Again, I think the really important point is there are no cases of insertional oncogenesis. And so these are cases that were related to the procedure.

Dkt. 34-6 at 15-16.

IV. FDA Approval of Lovo-Cel

On December 8, 2023, bluebird announced that the FDA had approved lovo-cel. The FDA rejected the company's application for a PRV, however, because it concluded that lovo-cel contained an active ingredient previously approved in the BLA for Zynteglo. The FDA also required bluebird to include a black box warning on the lovo-cel label about the risk of blood cancers. On this news, the price of bluebird's common stock declined from $4.81 to $2.86 per share. The same day, Vertex received FDA approval for its competing therapy for SCD. This approval came with a PRV and no black box warning. When asked about the commercial prospects for lovo-cel in relation to Vertex's therapy given lovo-cel's black box warning, Colvin stated that "[t]he potential for a box warning was something [bluebird] anticipated and it was built into [its] commercial projections." Dkt. 26 ¶ 81 (emphasis omitted).

DISCUSSION

Plaintiff brings two claims in his amended complaint, one under section 10(b) and Rule 10b-5 and the other under section 20(a). The latter claim is derivative of the former, see Zhou v. Desktop Metal, Inc., 120 F.4th 278, 296 (1st Cir. 2024); Quinones v. Frequency Therapeutics, Inc., 106 F.4th 177, 185 n.1

(1st Cir. 2024), so the Court focuses its analysis solely on the claim under section 10(b) and Rule 10b-5.

I. Legal Standards

To survive a Rule 12(b)(6) motion to dismiss, a "complaint 'must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" Analog Techs., Inc. v. Analog Devices, Inc., 105 F.4th 13, 17 (1st Cir. 2024) (quoting Douglas v. Hirshon, 63 F.4th 49, 55 (1st Cir. 2023)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). Because Plaintiff's amended complaint alleges securities fraud, it also must surmount the hurdles imposed by Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). See Zhou, 120 F.4th at 287.

A private plaintiff suing under section 10(b) and Rule 10b-5 "must allege: '(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Quinones, 106 F.4th at 182 (quoting In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017)). A plaintiff's failure to adequately allege any one of these elements is fatal to his claim. See Zhou, 120 F.4th at 287. Defendants challenge the

sufficiency of Plaintiff's allegations of both a material misrepresentation or omission and scienter.

Rule 9(b) requires a plaintiff "to plead the circumstances of the securities fraud with particularity." Id. Similarly, "under the PSLRA, [the plaintiff] must 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (second alteration in original) (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)); see 15 U.S.C. 78u-4(b)(1). As a corollary, courts review the plausibility of a complaint's allegations of falsity "statement by statement, considering each statement in turn." Zhou, 120 F.4th at 293. This analysis involves consideration of "[t]he immediate context of each statement -- namely, the balance of what was said on the particular occasion, and the immediate circumstances in which the particular statement was made." Id. (alteration in original) (quoting Shash v. Biogen, 627 F. Supp. 3d 84, 101 (D. Mass. 2022)). While "the PSLRA does not require plaintiffs to plead evidence[,] a significant amount of meat is needed on the bones of the complaint." Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 455 (1st Cir. 2017) (cleaned up).

Private securities fraud plaintiffs face "a rigorous pleading standard on allegations of scienter." Zhou, 120 F.4th at 287 (quoting ACA Fin. Guar. Corp., 512 F.3d at 58). Although a court must accept the complaint's factual allegations as true, see

Quinones, 106 F.4th at 182, the PSLRA mandates that the plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]." Shash, 84 F.4th at 11 (alteration in original) (quoting Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 9 (1st Cir. 2021)); see 15 U.S.C. § 78u-4(b)(2)(A). To assess if a complaint satisfies this standard, "a court must engage in 'a comparative evaluation' by weighing the 'inferences urged by the plaintiff' against 'competing inferences rationally drawn from the facts alleged.'" Shash, 84 F.4th at 13 (quoting Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 314 (2007)). The key question is whether, "viewing the complaint in its entirety, . . . a reasonable person would deem the inference of scienter 'cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" Id. (quoting Tellabs, Inc., 551 U.S. at 314).

II. Black Box Warning and Blood Cancers

Plaintiff first alleges that Defendants made material misstatements and omissions regarding the possibility that the FDA would require a black box warning on the lovo-cel label and the relationship between lovo-cel and blood cancers. Defendants dispute that any of the challenged statements or omissions were false or misleading and argue that, even if they were, Plaintiff has not alleged facts supporting a strong inference of scienter.

The Court agrees that none of the statements or omissions at issue were false or misleading and, therefore, does not address scienter.

Section 10(b) and Rule 10b-5 impose liability when a defendant "made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Ponsa-Rabell, 35 F.4th at 32-33 (quoting Ganem, 845 F.3d at 454). Courts evaluate "whether a statement is 'misleading'" from "the perspective of a reasonable investor." Id. (quoting Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 186 (2015)). "[S]ection 10(b) and Rule 10b-5 'do not create an affirmative duty to disclose any and all material information'" and, thus, "only prohibit omissions that engender 'half-truths.'" Zhou, 120 F.4th at 292 (first quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011); and then quoting Macquarie Infrastructure v. Moab Partners, L.P., 601 U.S. 257, 263 (2024)). In other words, "[a]n omission, even if material, is actionable only if it 'renders affirmative statements made misleading.'" Id. (quoting Macquarie Infrastructure, 601 U.S. at 265).

A. May 2023 Healthcare Conference

Plaintiff argues that Obenshain made an actionable omission at the May 2023 healthcare conference when he responded to a question asking whether there were "[a]ny specific elements of the label [for lovo-cel] that [he] fe[lt] like [were] important one

way or another in terms of being market limiting or giving [bluebird] more latitude to operate in the space." Dkt. 34-4 at 8. Obenshain stated:

> In terms of the label, I don't think there's any one particular area that the FDA would focus on overall. I think the -- if we look back at our ZYNTEGLO [advisory committee], it was the efficacy and safety, which is pretty standard. So I don't think there's any one element that they're going to actually hold [sic] in on versus others.

Id. Plaintiff contends that this response misleadingly omitted the possibility that the FDA would approve lovo-cel with a black box warning about blood cancers.

Obenshain's statement was not plausibly false or misleading. Given his repeated use of the phrases "I don't think" and "I think," id., a reasonable investor would have understood him to be conveying an opinion that lacked certainty about the FDA's focus with regard to the label. See Omnicare, Inc., 575 U.S. at 187; Carbonite, Inc., 22 F.4th at 7. While an opinion may still be actionable as securities fraud, see Carbonite, Inc., 22 F.4th at 7, the amended complaint offers no non-conclusory allegations suggesting that Obenshain's statement misrepresented either his true belief about the FDA's focus with respect to the label or any facts known to him about the FDA's labeling determination. In fact, Plaintiff alleges that the FDA did focus on both efficacy and safety in its review of the lovo-cel BLA. See Dkt. 26 ¶ 62 (citing a CW's statement that bluebird "experienced difficulties in trying

to prove to the FDA that [lovo-cel] worked and . . . did not cause a more fatal disease than the underlying disease the patient already had").

Nor is it plausible that a reasonable investor would have found Obenshain's statement misleading because he did not mention the possibility that the FDA would require a black box warning on the lovo-cel label. Obenshain gave no impression as to whether the FDA would require such a warning or how the FDA would respond to the two leukemia deaths in the clinical trials. And he was not obligated to enumerate all possible ways that safety concerns could manifest on lovo-cel's label. Cf. Zhou, 120 F.4th at 294 ("[A] company that reveals one fact is not required to 'reveal all others that, too, would be interesting, market-wise.'" (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc))).

B. Third Quarter 2023 Earnings Call

The other statements about lovo-cel's safety that Plaintiff contends were false or misleading occurred during bluebird's third quarter 2023 earnings call. An analyst asked about the two leukemia cases in the lovo-cel clinical trials and whether "there [was] a scenario where [bluebird] get[s] a label that includes risk of secondary malignances." Dkt. 34-6 at 15. Obenshain responded that there were "no cases of insertional oncogenesis," that the two leukemia cases resulting in deaths "were related to the procedure"

used in an "earlier phase," and that those patients were "not in [the] efficacy data set." Id. at 16. He also stated: "[I]t is likely that we will have a mention of [the leukemia deaths] in the safety events in the label. In what part of the label or where is yet to be determined, but certainly, they will be in there. That's something that we've known for quite a while." Id. Plaintiff posits that Obenshain's response misleadingly omitted that lovo-cel could be subject to a black box warning, misleadingly downplayed the severity of the two leukemia deaths, and falsely suggested that bluebird had evidence that lovo-cel did not carry a risk of blood cancers.[1]

Obenshain's failure to say expressly that the FDA could require a black box warning for lovo-cel was not an actionable omission. Plaintiff's argument seems to rest on Obenshain's use of the term "safety events" and a purported distinction between "safety events" and a "black box warning." But while Plaintiff alleges that "[s]afety events on a label differ greatly from a

[1] Plaintiff also appears to challenge Obenshain's comment on bluebird's third quarter earnings call that the company was "confident in the robustness and maturity of [its] BLA package and the [FDA] review process." Dkt. 34-6 at 15. Plaintiff likewise contends that this comment misleadingly indicated that bluebird had evidence that the leukemia cases in the clinical trials were caused by the prior transplant procedure rather than the gene therapy itself. This comment was not plausibly false or misleading for the reasons discussed below with regard to the more express statement that there were no cases of insertional oncogenesis in the clinical trials.

black box warning," Dkt. 26 ¶ 68, a black box warning is an aspect of the label. See id. ¶¶ 5 n.3, 80-82. Obenshain fully disclosed that the FDA may require lovo-cel's label to reflect the leukemia deaths in the clinical trials; indeed, he said that those deaths would "certainly" be on the label. Dkt. 34-6 at 16. And because Obenshain cautioned that it was "yet to be determined" on "what part of the label or where" the deaths would be mentioned, id., no reasonable investor would plausibly have thought that Obenshain was foreclosing the possibility that the FDA would require a black box warning. Having unambiguously disclosed the overall risk that the leukemia deaths would appear on lovo-cel's label, Obenshain was not required to specify all the parts of the label on which the deaths could be listed. See Hill v. Gozani, 638 F.3d 40, 60 n.5 (1st Cir. 2011) (explaining that "where some level of risk materialize[s]," courts do not "require[] complete disclosure of all of the details when the overall risk is disclosed and the nature of the future risk remains uncertain").

That leaves Obenshain's statement that there were "no cases of insertional oncogenesis" in the clinical trials. Plaintiff's claim that this statement was false -- i.e., that the leukemia cases were actually caused by the gene therapy itself rather than the prior transplant procedure -- is not supported by well-pleaded facts in the amended complaint. Plaintiff offers no factual basis for his conclusory allegation "that lovo-cel was the cause of death

for the three patients in [bluebird's] trials." Dkt. 26 ¶ 88. Notably, he does not allege that the FDA's decision to require a black box warning means that the FDA concluded that the leukemia cases were instances of insertional oncogenesis. Instead, the amended complaint describes "[t]he purpose of a black box warning" as "inform[ing] the public of a known risk associated with a drug." Id. ¶ 60. Plaintiff does not allege that the FDA found that the deaths were due to the gene therapy or that bluebird lacked any evidence that the leukemia cases were not instances of insertional oncogenesis.[2]

III. PRV Application

Plaintiff also alleges that Krawtschuk made two false statements regarding the PRV application that bluebird submitted with its lovo-cel BLA: first, his comment on bluebird's second quarter 2023 earnings call that "it[was] possible [bluebird] could

[2] Plaintiff's opposition to the motion to dismiss cites a statement made by an FDA official upon lovo-cel approval that there was "not, at [that] point, definitive evidence to say specifically . . . that [the cancer risk was] just due to the conditioning regimen" rather than the gene therapy itself. Matt Hoffman, FDA Experts Weigh in on Exa-cel and Lovo-cel Approvals for Sickle Cell and Corresponding Black Box Safety Warnings, CGTlive (Dec. 8, 2023), https://www.cgtlive.com/view/fda-experts-exa-cel-lovo-cel-approvals-sickle-cell-disease-safety-warnings. The Court does not consider this statement because it is not in the amended complaint. See Doe ex rel. A v. Spears, 630 F. Supp. 3d 290, 295-96 (D. Mass. 2022) (noting that courts generally do not consider facts raised for the first time in opposition to a motion to dismiss). In any event, the official did not say that the FDA had concluded that the leukemia cases were instances of insertional oncogenesis.

receive a PRV since lovo-cel BLA was accepted for priority review for patients 12 and over," Dkt. 34-5 at 16; and second, his comment on bluebird's third quarter 2023 earnings call that bluebird had "entered into an advanced agreement to sell a [PRV], if granted, for lovo-cel for sickle cell disease for $103 million," Dkt. 34-6 at 7. Both statements indicated -- the first statement explicitly and the second implicitly -- that it was possible bluebird could receive a PRV.[3]

Plaintiff's theory of falsity rests on the statutory requirements for a PRV. These requirements include that the new biologic "contains no active ingredient that has been previously approved in any other [biologic] application." 21 U.S.C. § 360ff(a)(4)(B)(ii)(I). In Plaintiff's view, Krawtschuk's statements were false because lovo-cel contains an active ingredient previously approved in the Zynteglo BLA. As the two therapies share an active ingredient, Plaintiff posits, it was never possible for bluebird to receive a PRV in connection with its lovo-cel BLA. Disputing this theory, Defendants argue that neither statement was false because, even though the FDA ultimately determined that lovo-cel and Zynteglo share an active ingredient,

[3] Plaintiff's amended complaint alleges that the statements at issue falsely promised investors that bluebird would receive a PRV. Plaintiff does not press this framing of his claim in opposing the motion to dismiss. Regardless, any such argument would be meritless: a reasonable investor plainly would not have understood either statement to guarantee that bluebird would receive a PRV.

that determination was not inevitable from the start. See City of Miami Fire Fighters' & Police Officers' Ret. Tr. v. CVS Health Corp., 46 F.4th 22, 30-31 (1st Cir. 2022) ("For allegedly false statements to support a claim of securities fraud, they must be 'false when made.'" (quoting Gross v. Summa Four, Inc., 93 F.3d 987, 994 (1st Cir. 1996))).

The Court lacks adequate information to evaluate whether Krawtschuk's statements about the PRV were false. Neither the amended complaint nor the parties' briefing describes how the FDA determines what active ingredients are in a biologic and whether any of those ingredients overlap with a previously approved product. At the hearing, Plaintiff argued that identifying a biologic's active ingredients involves no discretion, citing FDA guidance that defines an active ingredient as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function in the human body of man or other animals." Food & Drug Admin., Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs) 6 (2020), https://www.fda.gov/media/113760/download. Defendants responded that, at least for gene therapies like lovo-cel, deciding what active ingredients a biologic contains requires exercising scientific judgment. The Court cannot adopt either party's

position without relevant allegations in the amended complaint or other information cognizable on a motion to dismiss.

Even assuming there was no possibility from the start that bluebird would receive a PRV, Plaintiff has failed to plead facts supporting a strong inference of scienter. The scienter requirement asks whether "the defendants consciously intended to defraud . . . or acted with a high degree of recklessness." Shash, 84 F.4th at 13 (quoting Carbonite, Inc., 22 F.4th at 8). "In this context . . . recklessness is 'a highly unreasonable omission' amounting to 'an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" Id. (quoting Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 206 (1st Cir. 2020)). This definition "of recklessness is 'closer to a lesser form of intent' than it is to ordinary negligence." Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc., 838 F.3d 76, 80 (1st Cir. 2016) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 199 (1st Cir. 1999)). As previously noted, the PSLRA requires courts to ask whether, "viewing the complaint in its entirety, . . . a reasonable person would deem the inference of scienter 'cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" Shash, 84 F.4th at 13 (quoting Tellabs, Inc., 551 U.S. at 314).

Complaints satisfying the PSLRA's standard for pleading scienter generally include "admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." Id. at 15 (quoting In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016)). Plaintiff's amended complaint describes no such records or discussions suggesting that Krawtschuk -- or anyone at bluebird, for that matter -- was aware or recklessly disregarded that lovo-cel was ineligible for a PRV.

Plaintiff contends that Krawtschuk and others at bluebird must have known that lovo-cel was ineligible for a PRV because the requirement that the biologic not contain a previously approved active ingredient is unambiguous. Since a PRV is a valuable asset, it is reasonable to assume that certain bluebird officers and employees, including Krawtschuk, paid close attention to information about whether lovo-cel was eligible for a PRV.

Yet the amended complaint fails to "allege particular facts strongly suggesting that that attention exposed" Krawtschuk or others at bluebird "to information that either rendered [the] public statements false or necessarily invited further investigation." Carbonite, Inc., 22 F.4th at 9-10. Even if, as Plaintiff alleges, bluebird reused "the information, processes,

and technology from [its] prior drugs" to develop lovo-cel, Dkt. 26 ¶ 33, the amended complaint does not describe in any detail the actual composition of lovo-cel or the process for determining whether Defendants must have known that two biologics share an active ingredient. The Court therefore cannot infer that lovo-cel's ineligibility for a PRV would have been obvious when bluebird submitted its BLA for lovo-cel. Plaintiff also fails to recount any communication from the FDA before Krawtschuk made the statements at issue that should have made clear to bluebird that it would not be receiving a PRV. The fact that bluebird successfully negotiated an agreement to sell the hoped-for PRV bolsters the inference that bluebird thought it could possibly receive one. The likelihood is that bluebird would not have devoted resources to negotiating that agreement if it were aware that lovo-cel was ineligible for a PRV. Nor is it likely that bluebird's counterparty would have agreed to the deal if its due diligence had suggested that there was no possibility the FDA would award a PRV. The agreement to sell the PRV suggests that at least one other biotechnology company thought bluebird could receive a PRV for lovo-cel. That fact bolsters the inference that bluebird's belief that it was possible the FDA would award a PRV was genuine.

When "a complaint is devoid of any direct-evidence allegations" of scienter, "the indirect-evidence allegations in the complaint will need to do more work to carry the burden of

raising a 'strong inference of scienter' on their own." Shash, 84 F.4th at 16 (quoting Brennan v. Zafgen, Inc., 853 F.3d 606, 615 n.8 (1st Cir. 2017)). These allegations may include other "'facts and circumstances indicating fraudulent intent,' including those demonstrating 'motive and opportunity.'" Brennan, 853 F.3d at 614 (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). But "'catch-all allegations,' which merely assert the existence of a motive and an opportunity to engage in fraudulent behavior, do not satisfy the PSLRA 'without something more.'" Id. at 616 (quoting In re Cabletron Sys., Inc., 311 F.3d 11, 39 (1st Cir. 2002)); cf. Aldridge, 284 F.3d at 82 ("[W]hile mere allegations of motive and opportunity alone may be insufficient, together with additional factual support, evidence of motive and opportunity may establish a strong inference of scienter.").

Plaintiff's allegations about Defendants' motive to defraud investors do not suffice to overcome the absence of direct evidence of scienter. According to a CW, bluebird announced internally in June 2023 that it "would need a cash infusion and only had enough money to continue operations through February 1, 2024." Dkt. 26 ¶ 29. Even assuming this financial motive goes beyond the "ever-present desire to improve results" to suggest that "the very survival of the company w[as] on the line," Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 60 (1st Cir. 2018) (alteration in original) (quoting Corban v. Sarepta Therapeutics, Inc., 868 F.3d

31, 41 (1st Cir. 2017)), the resulting inference of scienter is significantly weakened by Plaintiff's failure to allege that bluebird actually raised money during the period between Krawtschuk's initial statement about a PRV and the FDA's announcement that it was not awarding one. Cf. Auto. Indus. Pension Tr. Fund v. Textron Inc., 682 F.3d 34, 40 (1st Cir. 2012) (explaining that, by itself, the argument that "the officers' careers and the survival of the company were on the line" was "hardly the particularized showing required by the PSLRA"). The amended complaint also describes bluebird's desire to compete with Vertex's superior therapy for SCD, but it is not clear why proclaiming the possibility that bluebird would receive a PRV would put bluebird in a stronger position to convince doctors and patients to use lovo-cel rather than Vertex's therapy.

Viewing the amended complaint holistically, see Quinones, 106 F.4th at 184, the Court finds the inference of scienter to be less compelling than the competing innocent inference. It is more likely that bluebird genuinely believed that there was a possibility that the FDA would conclude that lovo-cel and Zynteglo do not share an active ingredient. Plaintiff's allegation of scienter rests on the fact that the FDA ultimately reached the opposite conclusion. This

type of "fraud by hindsight" is insufficient to satisfy the PSLRA's high bar for pleading scienter. In re Biogen, 857 F.3d at 44.[4]

IV. Leave to Amend

Finally, Plaintiff requests leave to amend should the Court determine that he has not adequately pled his claims. The Court denies this request without an explanation of what changes he would make to rectify the deficiencies in his pleading of his claims. Plaintiff must show that a further amendment would not be futile. See Zell v. Ricci, 957 F.3d 1, 18 n.20 (1st Cir. 2020).

ORDER

For the foregoing reasons, bluebird's motion to dismiss (Dkt. 32) is **ALLOWED** without prejudice to the filing of a motion for leave to amend the complaint within thirty days.

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge

[4] In light of this outcome, the Court need not address Defendants' remaining arguments, including that the statements Plaintiff challenges are protected by the safe harbor in 15 U.S.C. § 78u-5.